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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,362	03/22/2004	Thierry Glauser	50623.351	3954

7590 09/25/2007

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EXAMINER	
KENNEDY, SHARON E	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
09/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/807,362	GLAUSER ET AL.	
	Examiner	Art Unit	
	Sharon E. Kennedy	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-99 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-99 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-20, drawn to a biocompatible polymer, classified in class 514, subclass 772+.

II. Claims 21-42, drawn to an implantable device having a coating, classified in class427, subclass 2.1.

III. Claims 43-65, drawn to an implantable device having a coating and including a bioactive agent, classified in class 424, subclass 422.

IV. Claims 66-91, drawn to a method of treating a disorder, classified in class 424, subclass 422.

V. Claim 92, drawn to a method of preparing a polymer or copolymer, classified in class 526, subclass 180.

VI. Claims 93-99, drawn to coating compositions, not in combination with an implantable device, classified in class 427, subclass 2.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product, and the species are patentably distinct (MPEP § 806.05(j)). In the instant case, the intermediate product is deemed to be useful as a polymer used to prepare an implantable device, instead of

application as a coating and the inventions are deemed patentably distinct because there is nothing on this record to show them to be obvious variants.

Inventions II and III are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product, and the species are patentably distinct (MPEP § 806.05(j)). In the instant case, the intermediate product is deemed to be useful as an implantable device which does not release medicament, such as hip replacement devices (see, for example, US 2004/0243249, and the inventions are deemed patentably distinct because there is nothing on this record to show them to be obvious variants.

Inventions (II or III) and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in other medical applications, such as a blood filtering apparatus, and not necessarily an implantable device.

Inventions I and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed in claim 1 requires a

biodegradable or nonbiodegradable polymer as a polymeric backbone, and the process of making is directed to a phosphoryl choline containing polymer, and does not require the aspects of the process.

Inventions I and VI are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product, and the species are patentably distinct (MPEP § 806.05(j)). In the instant case, the intermediate product is deemed to be useful as a biocompatible polymer to prepare the whole of an implant, not merely a coating for an implant, and the inventions are deemed patentably distinct because there is nothing on this record to show them to be obvious variants.

In addition to the above restriction, applicant must select one species for examination.

Election/Restrictions

This application contains a disclosure including claims directed to the following patentably distinct species containing various embodiments:

Phospholipid Moieties Embodiment: Applicant must select one of phosphoryl choline, phosphoryl serine, phosphoryl inositol, di-phosphoryl glycerol, zwitterionic phosphoryl ethanolamine.

Nondegradable Polymer Embodiment: Applicant must select one of the polymers listed in claims 3 or another polymer listed in the specification. Picking a class of polymers is not acceptable. For example, choosing "methylmethacrylate" would be acceptable, but choosing "acrylic polymers" would not be accepted.

Biodegradable Polymer Embodiment: Applicant must select one of the polymers listed in claim 4 or another polymer listed in the specification. Picking a class of polymers is not acceptable. For example, choosing "polylactide" would be acceptable, but choosing "polyesters" would not be accepted.

Additional Biobeneficial Moiety Embodiment: Applicant must select one of the biobeneficial moieties from, e.g., claims 8, 11 or any of the specific moieties listed in the specification. Again, picking "heparin" would be acceptable. Choosing "anti-thrombogenics" would not be accepted.

Bioactive Agent Embodiment: Applicant must select one of the bioactive agents listed in paragraphs [0043]. Again, one agent must be selected. Choosing "everolimus" would be acceptable. Choosing "antiproliferatives" would not be accepted.

Disorder Treated Embodiment: Applicant must select one of the disorders listed in claims 66-91.

Applicant must select one embodiment from each of the sets of embodiments to form the selected specie.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that a reply to this requirement must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and **(ii) identification of the claims encompassing the elected species,** including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented

at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse of the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

A telephone call was made to Cameron Kerrigan on September 20, 2007 to request an oral election to the above restriction requirement, but did not result in an election being made.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sharon E. Kennedy/
Sharon E. Kennedy
Primary Examiner
Art Unit 1615